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EXAMINER	
PORTER, RACHEL L	
ART UNIT	**PAPER NUMBER**
3626	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/699,372	HUDSON, COURTNEY	
	Examiner	Art Unit	
	Rachel L. Porter	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7-10,12-24,39,41-46 and 48-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-5, 7-10, 12-24, 39, 41-46, and 48-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1. This communication is in response to the amendment filed 8/9/06. Claims 1, 3-5, 7-10, 12-24, and 39, 41-46,48-60 are pending.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/9/06 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3-5, 7-10, 12-24, and 39, 41-46,48-60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Exemplary claim 1 recites the limitation of "presenting to the user a series of questions targeted to the at least one specific clinical trial after determining that the

patient prequalifies for any of the clinical trials." The examiner understands the phrase "the at least one specific clinical trial" to mean that the patient need only qualify for one trial to address the claim limitation. Furthermore, the examiner understands step of "presenting to the user a series of questions targeted to the at least one specific clinical trial" to be the same as providing the user with an application for participation, since the process of presenting a series of questions to the user need only qualify the user for one study to address the recited limitation.

Therefore, it is unclear to the examiner how the amended claim is intended to further narrow the previous claim language. In other words, it is unclear what action is taken with the step of "providing the user an application to apply for participation in the specific" and how the claimed "application" is distinct from the series of questions presented to the user, which qualify him/her for the study. For the purpose of examiner, the examiner has interpreted the "application for participation" as a consent or enrollment form.

The same analysis applies to claims 19, 24, and 39, which recite language similar to claim 1.

Dependent claims 3-5, 7-10, 12-18, 20-23, 41-46, and 48-60

5. Claim 48 recites the limitation "the method of claim 19" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 19 recites *a system* not a method.

Moreover, it is noted that while exemplary claim 19 recites a "system" in the preamble, claim 48 recites a step performed by a user in the system, not a system component. It is therefore unclear how the recited step limitations of claim 48 are intended to further define or distinguish the "system" of claim 19.

A similar analysis may be applied to claim 53, which simply recites that the user is provided with search engine that allows the user to search for medical information. It is unclear how a component of the system/apparatus is further defined by the recited limitation.

Therefore, it is unclear whether the applicant intends to claim a process or a system/apparatus in claims 48-53.

Claims 49-52 inherit the deficiencies of claim 48 through dependency, and are therefore also rejected.

For examination purposes, the Examiner will interpret claims 48-52 as being dependent from claim 19.

Also, claim 60 recites a computer executable software code, wherein the user is provided with search engine that allows *the user* to search for medical information. It is unclear how the computer readable code is further defined by the recited limitation. In other words, as currently recited, it is unclear which aspect of the claim 60 is performed by the executable software code.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 3-5, 7-10, 12-14, 17-24,39,41-43,46,48-50,53-57, and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight (USPAP 2002/0099570) in view of Schmidt. (USPN 6,839,678)

[claim 1] Knight discloses a method for matching patients with clinical trials, comprising:

- receiving patient profile information for a patient at a server connected to a computer network, the patient profile information submitted by a user at a terminal connected to the network; (par. 68)
- comparing the patient profile information with acceptance criteria for clinical trials stored in a database, the comparison performed by the server; and (par. 63,69))
- automatically, determining whether the patient prequalified for any of the clinical trials based on the comparison of the patient profile information with the acceptance criteria; and (par. 63)
- if the patient prequalified, for any of the clinical trials notifying the user that the patient has prequalified for at least one specific clinical trial; (par. 73—trial contact information appears)

- presenting to the user a series of questions targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials; (par. 70)
- determining whether the user prequalifies for at least one specific clinical trial based on the users response to the targeted questions; and (par. 70)
- storing the responses to the targeted questions. (par. 70-73)

Claim 1 has been amended to recite that if the user prequalifies for at least one specific clinical trial, the user is provided with an application for participation in the specific drug trial. Knight discloses a system/method which presents a series of targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials (par. 70).

However, Knight does not expressly disclose providing the user with an application to apply/ consent for participation in the specific clinical trial. Schmidt discloses a system/method wherein the prequalified patient is sent an application for the clinical trial in question after it is determined that he/she is qualified for the study. (Col. 4, lines 64-col. 5, line 9) The patient is provided documents including Declaration to Consent, which must be affirmed before they are enrolled in the study. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight the teachings Schmidt to provide a study specific application to the patient (e.g. consent/enrollment form) to the patient once they have prequalified for at least one study. As suggested by Schmidt, one would have been

motivated to include this feature to provide a simpler and more effective manner of completing medical studies, which allows sufficient numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

[claim 3] Knight teaches a method further including providing the user with instructions for enrolling in the clinical trial for which the user has prequalified. (par. 73—the user is sent contact information if he/she qualifies)

[claim 4] Knight teaches a method further including asking the user a plurality of questions and creating a patient profile based on the responses to the plurality of questions. (figure 1; par. 68—e.g. gathering demographic data)

[claim 5] Knight teaches a method of claim 4, wherein the step of asking the user a plurality of questions includes: asking the user one or more static questions; asking the user one or more dynamic questions which are selected based on the user's responses to other static and dynamic questions; and creating a the patient profile based on the responses to the static and dynamic questions. (Figures 1, par. 68, 72-75)

[claim 7] Knight teaches a method of wherein static questions, dynamic questions, and targeted questions are provided with a plurality of answer options, and the user may select one or more answer options in order to answer the questions. (Figure 3-6; par. 75-77)

[claim 8] Knight teaches a method of claim 7, wherein the user is required to submit an answer in a specified format, the specified format being suitable for evaluation by a computer program process. (par. 57: e.g. web-based interface)

[claim 9] Knight teaches a method further including updating the static questions, dynamic questions, or answer options. (par. 84-85)

[claim 10] Knight teaches a method wherein the network is the Internet. (par. 57: e.g. web-based interface; par.75—web pages presented)

[claims 12-13] Knight teaches a method wherein the user answers several steps of questions on-line. Knight further discloses that information is submitted by the user on-line and that this data is stored on a server. (Figures 29-30) However, Knight does not expressly disclose providing the user with an application to apply/ consent for participation in the specific clinical trial. Schmidt discloses a system/method wherein the prequalified patient is sent an application/consent form for the clinical trial in question, wherein the patient fills out the application/consent online and, wherein the application is sent to a clinical trial site. (Col. 4, lines 64-col. 5, line 15) The patient is provided documents including Declaration to Consent, which must be affirmed before they are enrolled in the study. At the time of the Applicant's invention, it would have

been obvious to one of ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the patient fill-out an online application (e.g. consent/enrollment form) and to forward this form to the clinical site. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of completing medical studies, which allows sufficient numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

[claim 14] Knight teaches a method wherein the patient profile is forwarded to clinical trial site (par. 109,125,), but does not expressly disclose that the profile information is sent with the application/consent form. Schmidt discloses a method wherein the patient profile is sent with the application/consent form to the clinical trial site. (col. 5, lines 6-22) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the patient online application (e.g. consent/enrollment form) and patient profile forwarded to the clinical site. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of completing medical studies, by facilitating patient data validation. (col. 1, lines 65-67; col. 2, lines 27-34)

[claim 17] Knight discloses a method wherein the user is provided with a search engine that allows the user to search for medical information before selecting a clinical trial. (par. 65-68)

[claim 18] Knight teaches a method wherein the acceptance/matching criteria include geographic location. (par. 76/Fig. 4—geographic location and preferences are match criteria)

[claim 19] Knight discloses a system for matching patients with clinical trials, comprising:

- a server connected to a network;(Figure 29)
- a data storage device included in the server, and (Figure 29)
- a database located in the data storage device, the database storing patient profile information for a patient and acceptance criteria for a plurality of clinical trials; (Figures 29-30, par. 68)
- the server comparing the patient profile information with the acceptance criteria for the clinical trials stored in the database, (par. 63,69)
- automatically, determining whether the patient prequalifies for any of the clinical trials based on the comparison of the patient profile information with the acceptance criteria; and (par. 63)
- if the patient preaqualifies for any of the clinical trials, notifying the user that the patient has prequalified for at least one specific clinical trial; (par. 73—trial contact information appears)

- presenting to the user a series of questions targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials; (par. 70)
- determining whether the user prequalifies for the at least cone specific clinical trial based on the user's response to the targeted questions: and (par. 70)
- storing the responses to the targeted questions (par. 70-73)

Claim 19 has been amended to recite that if the user prequalifies for at least one specific clinical trial, the user is provided with an application for participation in the specific drug trial. Knight discloses a system/method which presents a series of targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials (par. 70).

However, Knight does not expressly disclose providing the user with an application to apply/ consent for participation in the specific clinical trial. Schmidt discloses a system/method wherein the pre-qualified patient is sent an application for the clinical trial in question after it is determined that he/she is qualified for the study. (Col. 4, lines 64-col. 5, line 9) The patient is provided documents including Declaration to Consent, which must be affirmed before they are enrolled in the study. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Knight the teachings Schmidt to provide a study specific application to the patient (e.g. consent/enrollment form) to the patient once they have pre-qualified for at least one study. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of

completing medical studies, which allows sufficient numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

[claim 20] Knight teaches a system wherein the database contains information on disease records; drug records; clinical trial records; and patient profile records. (par. 66; 75-77)

[claim 21] Knight teaches a system wherein a record in the database contains links to other related records. (Fig. 30)

[claim 22] Knight teaches a system wherein the server transmits a plurality of questions to the user over the network, the server also transmits a plurality of answer choices for each question, the server receives responses from the user, and the server builds a patient profile based on the responses. (Figures 1, par. 68, 72-75)

[claim 23] Knight teaches a system wherein the server retrieves a disease/subdisease record corresponding to a disease/sub-disease entered by the user, the disease/-sub-disease record containing links to question records, the server retrieving the question records to access questions to be provided to the user. (Figures 1-2; par. 72)

[Claim 24, 54] The limitations of claim 24 and 54 recite a computer executable software instructions for causing a computer to perform the method recited in claim 1. Insofar as the method of claim 1 has been shown to be fully disclosed and computer implemented

by the teachings of Knight in view of Schmidt in the rejection of claim 1, it is submitted that claims 24 and 54 are rejected for the same reasons provided in the rejection of claim 1, and incorporated herein.

[claim 39] Knight teaching method comprising the steps of:

- presenting at least one web page to permit an individual to be registered with a database by submitting information indicating whether notice of one or more clinical studies is desired and registration information, wherein the registration information includes at least a geographic location, a disease condition of interest, and contact Information; (par. 55, par. 128-131)
- automatically registering the individual with the database upon receipt of the registration and indicating information; (par. 131)
- automatically determining, in accordance with the indicating information and the registration information whether to provide notice of a clinical study related to said disease condition; (par. 133)
- providing notice of said clinical study; (par. 133)
- presenting a screening questionnaire associated with said clinical study; and (Figure 10)
- storing in the database answers submitted in response to said questionnaire. (par. 80)

Claim 39 has been amended to recite that based upon responses to the screening questionnaire, the user is provided with an application for participation in the specific

clinical trial. Knight discloses a system/method which presents a series of targeted to the at least one specific clinical trial after determining that the patient prequalifies for any of the clinical trials (par. 70).

However, Knight does not expressly disclose providing the user with an application to apply/ consent for participation in the specific clinical trial. Schmidt discloses a system/method wherein the pre-qualified patient is sent an application for the clinical trial in question after it is determined that he/she is qualified for the study. (Col. 4, lines 64-col. 5, line 9) The patient is provided documents including Declaration to Consent, which must be affirmed before they are enrolled in the study. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Knight the teachings Schmidt to provide a study specific application to the patient (e.g. consent/enrollment form) to the patient once they have pre-qualified for at least one study. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of completing medical studies, which allows sufficient numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

[claims 41-42] Knight teaches a method wherein the user answers several steps of questions on-line. Knight further discloses that information is submitted by the user on-line and that this data is stored on a server. (Figures 29-30) However, Knight does not expressly disclose providing the user with an application to apply/ consent for participation in the specific clinical trial. Schmidt discloses a system/method wherein

the prequalified patient is sent an application/consent form for the clinical trial in question, wherein the patient fills out the application/consent online and, wherein the application is sent to a clinical trial site. (Col. 4, lines 64-col. 5, line 15) The patient is provided documents including Declaration to Consent, which must be affirmed before they are enrolled in the study. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the patient fill-out an online application (e.g. consent/enrollment form) and to forward this form to the clinical site. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of completing medical studies, which allows sufficient numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

[claim 43] Knight teaches a method wherein the patient profile is forwarded to clinical trial site (par. 109,125,), but does not expressly disclose that the profile information is sent with the application/consent form. Schmidt discloses a method wherein the patient profile is sent with the application/consent form to the clinical trial site. (col. 5, lines 6-22) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the patient online application (e.g. consent/enrollment form) and patient profile forwarded to the clinical site. As suggested by Schmidt, one would have been motivated to include

this feature to provide a simpler and more effective manner of completing medical studies, by facilitating patient data validation. (col. 1, lines 65-67; col. 2, lines 27-34)

[claim 46] Knight further discloses a wherein the user is provided with a search engine that allows the user to search for medical information before selecting a clinical study. (par. 65-68)

[claims 48-49] Knight teaches a system wherein the user answers several steps of questions on-line. Knight further discloses that information is submitted by the user on-line and that this data is stored on a server. (Figures 29-30) However, Knight does not expressly disclose providing the user with an application to apply/ consent for participation in the specific clinical trial. Schmidt discloses a system/method wherein the pre-qualified patient is sent an application/consent form for the clinical trial in question, wherein the patient fills out the application/consent online and, wherein the application is sent to a clinical trial site. (Col. 4, lines 64-col. 5, line 15) The patient is provided documents including Declaration to Consent, which must be affirmed before they are enrolled in the study. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the patient fill-out an online application (e.g. consent/enrollment form) and to forward this form to the clinical site. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of completing medical studies, which allows sufficient

numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

[claim 50] Knight teaches a method wherein the patient profile is forwarded to clinical trial site (par. 109,125,), but does not expressly disclose that the profile information is sent with the application/consent form. Schmidt discloses a method wherein the patient profile is sent with the application/consent form to the clinical trial site. (col. 5, lines 6-22) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the patient online application (e.g. consent/enrollment form) and patient profile forwarded to the clinical site. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of completing medical studies, by facilitating patient data validation. (col. 1, lines 65-67; col. 2, lines 27-34)

[claim 53] Knight further discloses a system claim 19, wherein the user is provided with a search engine (i.e. that allows the user to search for medical information before selecting a clinical study.) (par. 65-68)

[claims 55-56] Knight and Schmidt disclose a computer executable software code of claim 24 as explained in the rejection of claim 24.

Knight teaches a method wherein the user answers several steps of questions on-line. Knight further discloses that information is submitted by the user on-line and

that this data is stored on a server. (Figures 29-30) However, Knight does not expressly disclose providing the user with an application to apply/ consent for participation in the specific clinical trial. Schmidt discloses a system/method wherein the prequalified patient is sent an application/consent form for the clinical trial in question, wherein the patient fills out the application/consent online and, wherein the application is sent to a clinical trial site. (Col. 4, lines 64-col. 5, line 15) The patient is provided documents including Declaration to Consent, which must be affirmed before they are enrolled in the study. At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the patient fill-out an online application (e.g. consent/enrollment form) and to forward this form to the clinical site. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of completing medical studies, which allows sufficient numbers of patients for medical studies to be obtained more quickly. (col. 1, lines 65-67; col. 2, lines 13-19)

[claim 57] Knight and Schmidt disclose a computer executable software code of claim 24 as explained in the rejection of claim 24.

Knight teaches a method wherein the patient profile is forwarded to clinical trial site (par. 109,125,), but does not expressly disclose that the profile information is sent with the application/consent form. Schmidt discloses a method wherein the patient profile is sent with the application/consent form to the clinical trial site. (col. 5, lines 6-22) At the time of the Applicant's invention, it would have been obvious to one of

ordinary skill in the art to modify the method of Knight the teachings Schmidt to have the patient online application (e.g. consent/enrollment form) and patient profile forwarded to the clinical site. As suggested by Schmidt, one would have been motivated to include this feature to provide a simpler and more effective manner of completing medical studies, by facilitating patient data validation. (col. 1, lines 65-67; col. 2, lines 27-34)

[claim 60] Knight and Schmidt disclose a computer executable software code of claim 24 as explained in the rejection of claim 24.

Furthermore Knight discloses a method wherein the user is provided with a search engine that allows the user to search for medical information before selecting a clinical study. (par. 65-68)

8. Claims 15-16, 44-45,51-52, and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight and Schmidt as applied to claims 1, 19, 24, and 39 and in further view of Kraftson et al (USPN 6,151,581).

[claim 15] Knight discloses a method wherein non-identifying patient information maybe forwarded to the trial site (par. 82) and also discloses that the system is designed to protect patient sensitive patient data (par. 125). However, Knight does not expressly disclose that the patient record and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's

identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight with the teaching of Kraftson and Schmidt to store the patient's information with a patient ID number. As suggested by Kraftson, one would have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 16] Knight teaches a method/ system further including notifying the clinical trial sponsor when the user submits patient information/registration information to the clinical trial site. (par. 131 e.g. sharing data with pharmaceutical companies) However, Knight does not expressly disclose that the sponsor is notified when the patient enrolls/ consents to participation in the study. Schmidt discloses a system and method in which patient data are made available and the patient is assigned to an appropriate group when they have consented to participate in the study. (i.e. notification). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Knight with the teaching of Schmidt to notify clinical trial sponsors when users have submitted an application/enrolled in the study. As suggested by Schmidt, one would have been motivated to include this feature to ensure that unnecessary data is not provided from a patient who is not qualified or willing to participate in the study. (col. 5, lines 11-15)

[claim 44] Knight discloses method a wherein non-identifying patient information maybe forwarded to the trial site (par. 82) and also discloses that the system is designed to protect patient sensitive patient data (par. 125). However, Knight does not expressly disclose that the patient registration information and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight and Schmidt with the teaching of Kraftson to store the patient's information with a patient ID number. As suggested by Kraftson, one would have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 45] Knight teaches a method further including notifying the clinical study sponsor when the user submits patient information/registration information to the clinical study site. (par. 131). However, Knight does not expressly disclose that the sponsor is notified when the patient enrolls/ consents to participation in the study. Schmidt discloses a system and method in which patient data are made available and the patient is assigned to an appropriate group when they have consented to participate in the study. (i.e. notification). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Knight with the teaching of Schmidt to notify clinical trial sponsors when users have submitted an

application/enrolled in the study. As suggested by Schmidt, one would have been motivated to include this feature to ensure that unnecessary data is not provided from a patient who is not qualified or willing to participate in the study. (col. 5, lines 11-15)

[claim 51] Knight discloses system a wherein non-identifying patient information maybe forwarded to the trial site (par. 82) and also discloses that the system is designed to protect patient sensitive patient data (par. 125). However, Knight and Schmidt do not expressly disclose that the patient registration information and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the system of Knight and Schmidt in combination with the teaching of Kraftson to store the patient's information with a patient ID number. As suggested by Kraftson, one would have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 52] Knight discloses a server notifying the clinical study sponsor when the user submits patient information/registration information to the clinical study site. (par. 131). However, Knight does not expressly disclose that the sponsor is notified when the patient enrolls/ consents to participation in the study. Schmidt discloses a system and

method in which patient data are made available and the patient is assigned to an appropriate group when they have consented to participate in the study. (i.e. notification). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Knight with the teaching of Schmidt to notify clinical trial sponsors when users have submitted an application/enrolled in the study. As suggested by Schmidt, one would have been motivated to include this feature to ensure that unnecessary data is not provided from a patient who is not qualified or willing to participate in the study. (col. 5, lines 11-15)

[claim 58] Knight and Schmidt teach a computer readable medium with executable code as explained in the rejection of claim 24.

Furthermore, Knight discloses method a wherein non-identifying patient information maybe forwarded to the trial site (par. 82) and also discloses that the system is designed to protect patient sensitive patient data (par. 125). However, Knight does not expressly disclose that the patient registration information and application include a patient ID to conceal the patient's identity. Kraftson teaches a system/method wherein a random ID number is assigned to a patient's profile and questionnaire to conceal/protect the patient's identity. (col. 12, lines 53-62) At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Knight and Schmidt with the teaching of Kraftson to store the patient's information with a patient ID number. As suggested by Kraftson, one would

have been motivated to include this feature to ensure that the patient is free to answer questions honestly and accurately with fear that his/her information will be divulged. (col. 12, lines 35-49)

[claim 59] Knight and Schmidt teach a computer readable medium with executable code as explained in the rejection of claim 24.

Furthermore, Knight discloses a method further including a server notifying the clinical study sponsor when the user submits patient information/registration information to the clinical study site. (par. 131) However, Knight does not expressly disclose that the sponsor is notified when the patient enrolls/ consents to participation in the study. Schmidt discloses a system and method in which patient data are made available and the patient is assigned to an appropriate group when they have consented to participate in the study. (i.e. notification). At the time of the Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method/system of Knight with the teaching of Schmidt to notify clinical trial sponsors when users have submitted an application/enrolled in the study. As suggested by Schmidt, one would have been motivated to include this feature to ensure that unnecessary data is not provided from a patient who is not qualified or willing to participate in the study. (col. 5, lines 11-15)

Response to Arguments

9. Applicant's arguments with respect to claims 1,19,24, and 39 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure

- Huyn et al (US 2002/0035486 A1) discloses a system for dynamic presentation of questions in a clinical questionnaire.
- Briegs et al (US 7054823 B1) discloses a comprehensive clinical trials planning and data management system.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel L. Porter whose telephone number is (571) 272-6775. The examiner can normally be reached on M-F, 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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RP

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